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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,754	08/24/2001	Samuel J. Danishefsky	2003080-0083 (SK-943-US)	4106
24280	7590	10/20/2004	EXAMINER	
Choate, Hall & Stewart Exchange Place 53 State Street Boston, MA 02109			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/938,754

**Applicant(s)**

DANISHEFSKY ET AL.

**Examiner**

Brenda Coleman

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,7-22,24-28,30,33-35,38,57-59 and 61-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22,24-28,57 and 67-70 is/are allowed.
- 6) ☒ Claim(s) 1,13,18,20,21,30,33-35,38,58,59,61-66 and 71-74 is/are rejected.
- 7) ☒ Claim(s) 2,3,7-12,14-17 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-3, 7-22, 24-28, 30, 33-35, 38, 57-59 and 61-74 are pending in the application.

This action is in response to applicants' amendment filed August 5, 2004. Claims 1, 18, 22, 24-28, 57-59 and 61 have been amended, claims 4 and 60 have been canceled and claims 63-74 are newly added.

### ***Response to Amendment***

Applicant's amendments filed August 5, 2004 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 30, 33-35, 38 and 59-62 labeled paragraph 3 maintained in the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. Applicants argue that references detailing the efficacy of radicicol, monocillin, and analogues thereof in the treatment of Hsp90-dependent cancers include: Yamamoto et al., *Angew. Chem. Int. Ed.* 42(11):1280, 2003; Buchner, *TIBS* 24:136, 1999; Chiosis et al., *Chem. & Biol.* 8:289, 2001; Roe et al., *J Med. Chem.* 42:260, 1999 and provisional U.S. Patent Application No. 60/531,092 filed December 19, 2003 is sufficient in the enablement of the claimed invention.

The applicant's arguments in reference to the journal articles Buchner and Roe are not persuasive in that Buchner states that "radicicol, initially thought to be a kinase inhibitor, also was shown to bind to the Hsp90 ATP-binding site" and that "it remains to be seen whether it also is functionally equivalent to geldanamycin". Roe states that "little medicinal chemistry has been reported for

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radicicol" and that radicicol is speculative at best in the use of radicicol in its antitumor activity by disruption of Hsp90-mediated activation of protein kinases.

Yamamoto et al., Chiosis et al., and provisional U.S. Patent Application No.

60/531,092 are not persuasive in that the articles and provisional applicaiton

were not public knowledge at the time of filing. Hence, at the time of filing the

state of the art with regards to radicicol was that it is suspected that this

compound may be associated with Hsp90. See MPEP 2164.05(a)

2164.05(a) Specification Must Be Enabling as of the Filing Date

The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date.

Publications dated after the filing date providing information publicly first

disclosed after the filing date generally cannot be used to show what was known

at the time of filing. In re Gunn , 537 F.2d 1123, 1128, 190 USPQ 402, 405 06

(CCPA 1976); In re Budnick, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA

1976) (In general, if an applicant seeks to use a patent to prove the state of the

art for the purpose of the enablement requirement, the patent must have an issue

date earlier than the effective filing date of the application.). While a later dated

publication cannot supplement an insufficient disclosure in a prior dated

application to make it enabling, applicant can offer the testimony of an expert

based on the publication as evidence of the level of skill in the art at the time the

application was filed. Gould v. Quigg, 822 F.2d 1074, 1077, 3 USPQ2d 1302,

1304 (Fed. Cir. 1987).

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Claims 30, 33-35, 38, 59, 61-66 and 71-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. With regards to the rejection of claims 1, 4, 13, 18, 21, 30, 33-35, 38 and 59-62 under 35 U.S.C. § 102(b), labeled paragraph 6 maintained in the last office action, the applicants' stated that the proviso (1) of claim 1 has been amended. However the proviso does not exclude the compounds taught by Sugimura where  $R_B$  and  $R_D$  are heteroarylalkyl, etc. See for examples the compounds 1128, 129, 130, 131, 213, 214, 215, 219, 220, 221, 222, 223, 224, 255, 226 in Table 1 **to name a few**.

Claims 1, 13, 18, 21, 30, 33-35, 38, 59, 61, 62, 73 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugimura et al., U.S. Patent No. 5,650,430 and 5,597,846, for reasons of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102(b) rejection of claims 1, 4, 7, 13, 18, 21, 30 and 59-61, labeled paragraph 7 in the last office action, which is hereby **withdrawn**.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112 first paragraph rejection of claims 57 and 58 labeled paragraph 8 in the last office action, which is hereby **withdrawn**.

5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a), b), c), d), e), g), h), and i) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled f) the applicant's amendments and remarks have been fully considered but they are not persuasive.

f) The applicants' stated that the claims as written would be clear and definite to one of skill in the art reading the claims in light of the application. However, the claims generically claim the method of treating a disorder responsive to the activity of Hsp90. The rejection of claims 30, 33-35, 38 and 59-62 was on the grounds that it is indefinite, in that it is not known which diseases are capable of being responsive to the activity of Hsp90. The scope of diseases and/or disorders associated with the inhibition of the activity of Hsp90. The applicants' are not entitled to preempt the efforts of others.

Claims 30, 33-35, 38, 59, 61-66 and 71-74 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

In view of the amendment dated August 5, 2004, the following new grounds of rejections apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 20 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

a) Claim 20 recites the limitation "lower alkyl" in the definition of R<sub>5</sub> and R<sub>6</sub>. There is insufficient antecedent basis for this limitation in the claim.

b) Claim 58 is a duplicate of claim 22.

***Claim Objections***

7. Claims 2, 3, 7-12, 14-17 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Allowable Subject Matter***

8. Claims 22, 24-28, 57 and 67-70 are allowed. None of the prior art or record or a search in the pertinent art area teaches the compounds of the instant invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman  
Primary Examiner  
Art Unit 1624  
October 18, 2004